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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,361	08/11/1999	BURKHARD SCHLUTERMANN	4-21233/A	4260

1095 7590 11/05/2002

THOMAS HOXIE  
NOVARTIS CORPORATION  
PATENT AND TRADEMARK DEPT  
564 MORRIS AVENUE  
SUMMIT, NJ 079011027

EXAMINER

SPEAR, JAMES M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/05/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/367,361

Applicant(s)  
SCHLUTERMANN, B

Examiner  
JAMES M. SPEAR

Art Unit  
1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 20, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-20 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourquin US 5,472,714. The claims are rejected for the reasons set forth in Paper No. 10.

Applicant's arguments filed August 20, 2002 have been fully considered but they are not persuasive. Applicants claims 16-20 are added by amendment and applicants feel that Bourquin teaches a double layered oxcarbazepine tablet. The Bourquin tablet comprises oxcarbazepine, a hydrophilic permeable inner layer and a hydrophilic permeable outer layer. Applicants further state that, "in contrast to the teaching of Bourquin, applicants have unexpectedly determined that only one hydrophilic coating is necessary provided that the oxcarbazepine has a median particle size of approximately 2 microns to 12 microns and a maximum residue on a 40 micron sieve of less than or equal to 5 %." How the coated tablet is made is not a basis for determining patentability of the composition. Applicants' apparent removal of a layer does not distinguish over the prior art. The film forming coating materials for the inner and outer layer of Bourquin are the same. See column 4,

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lines 53-61. The white pigments and iron oxide pigments of applicants' claim 20 are the same as Bourquin's. No evidence of the criticality in the number of layers has been presented. Varying the number of layers for aesthetic purposes does not distinguish the invention. The efficacy of a coating arises from properties such as thickness of different layers and the distinctions between the different layer forming components used. Since the same components are used, it would be reasonable to expect one skilled in the art would readily determine different modifications in the number of layers of coatings to effectively provide a stable oxcarbazepine tablet formulation if the number of layers affect stability.

Claims 16-20 are rejected.

Claims 1-15 have been canceled.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory

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period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Spear whose telephone number is 703 308 2457. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308 2927. The fax phone number for the organization where this application or proceeding is assigned is 703 305 3592 or 703 308 4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.

James M. Spear

November 2, 2002

*James M. Spear*  
JAMES M. SPEAR  
PRIMARY EXAMINER  
ART UNIT 1615